

35 U.S.C. 112, First Paragraph, Rejections Relative to the Specification

The Examiner has rejected the specification under 35 U.S.C. 112, first paragraph, as allegedly failing to provide an adequate written description and as allegedly failing to provide an enabling disclosure. As such, the Examiner indicates that the claimed invention 1) is insufficiently described such that one skilled in the art could reasonably deduce that the inventor had possession of the claimed subject matter as of the filing date, and 2) is not enabled such that one skilled in the art could make and use the invention described by the claims.

The Examiner takes specific objection to the illustration of a flat plug in Figure 3. The Examiner seems to indicate the specification is flawed under 35 U.S.C. 112, first paragraph, by describing what the Examiner believes to be a less desirable form than the best mode (as best mode, the Examiner points to the Embodiments of Figures 1 and 2, wherein a rounded end is provided at the treatment end of the housing tube to assist in maneuverability, e.g., through a catheter).

However, the specification is not flawed under 35 U.S.C. 112, first paragraph, where embodiments other than what may be the perceived best mode are described in addition to the perceived best mode. The rejection is improper. The Applicant respectfully requests withdrawal of the rejection.

Claim Objections

The Examiner correctly objected to the amendment in Paper No. 6, in that the amendment should have been made to claim 13 rather than to claim 14. Accordingly, the amendment has been reproduced herein relative to claim 13. The Applicant thanks the Examiner for indicating the error.

35 U.S.C. 112, First Paragraph, Rejections Relative to the Claims

Claims 1-31 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter allegedly not described in the specification such that one skilled in the art could make the invention. The Examiner referred to the earlier 35 U.S.C. 112 rejection of the specification dealing with a flat-ended source wire. The Applicant respectfully refers the Examiner to the remarks, above, addressing the Examiner's concerns.

35 U.S.C. 112, Second Paragraph, Rejections Relative to the Claims

Claims 1-31 were rejected under 35 U.S.C. 112, second paragraph, as allegedly failing to definitely claim subject matter. The Examiner noted concern with language describing "future acts" (specifically, the terminology "when bent"), indicating that such is not a positive structural limitation.

As a first point, whether the source wire is bent or straight is not a temporal limitation. The wire could be presently bent or presently straight (i.e., when claimed). There is no future action implied. Rather, such is a limitation that serves to define a characteristic of the materials of certain source wire components. In that respect, *In re Collier* does not apply.

As a second point, the decision in *In re Collier* is conditioned by the subsequent case *In The Matter Of The Application Of J. William Venezia*, 530 F.2d 956; 189 U.S.P.Q. (BNA) 149 (CCPA 1976). That case specifically discussed the *In re Collier* decision, noting that "conditional" language itself is not suspect, where such claims "precisely define present structural attributes of interrelated component parts...such that later assembly...may be effected." *Id* at 960.

For the above reasons, the rejection is improper and should be withdrawn.

Reconsideration and allowance is respectfully requested.

Claim Rejections under 35 U.S.C. 102

Claims 1-6, 9-15, 17-25 and 27-31 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Liprie '781.

Review of the independent claims reveals that the presently pending claims patentably distinguish over Liprie '781. As will be pointed out below, Liprie '781 lacks particular required limitations described by the independent claims. Because all of the required claim limitations are not described by the cited reference, an anticipation rejection is improper.

Each of independent claims 1 and 13 and 24 may be readily distinguished over Liprie '781 in that Liprie '781 fails to teach or suggest either of a "housing tube constructed from a material having little or no memory retention when bent." With respect to claim 24, Liprie '781 fails to teach or suggest either of a "housing tube constructed from a material having little or no memory retention when bent" or "a capsule inserted into said proximal end of the flexible elongated housing tube."

Rather, Liprie '781 teaches a housing tube constructed of either of stainless steel, tantalum or titanium (not a shape memory material). See Col. 6, lines 24-29.

This is wholly distinct from the above-stated requirements of claims 1, 13 or 24. Because these limitations are not taught or suggested (that is, since all of the limitations have not been identified in the cited art), the Examiner's rejections should be withdrawn.

Further with regard to the above, the Examiner stated in the Official Action, that Liprie '781 teaches encapsulation of radioactive sources, generally. The Applicant notes that while the reference does teach providing a radioactive source within a capsule, it does not teach placing that capsule material within a housing tube. Rather, the specification (at Column 4, lines 10-24) teach a wire like that of U.S. Patent No. 4,861,520 to Van't Hooft (hereinafter Van't Hooft), which was the sole U.S. reference of record in the '781 patent. That reference describes a capsule holding a radioactive source, which is either simply welded to a sheared end of a drive cable, or which is welded to a plug which is simply welded to a sheared end of a drive cable (all components stainless steel). Thus, neither Liprie '781, nor Van't Hooft, which displayed the type of construction referred to by Liprie '781, teaches the source wire construction provided for by the present claims.

Further Claim Rejection of Claims 1-6, 9-15, 17-25 and 27-31 Under 35 U.S.C. 103(a) as Allegedly Obvious over Liprie '781 in View of Nariciso and/or Ishibe.

In order to make out a prima facie case of obviousness, a proposed combination of prior art references must teach or suggest all of the limitations of the rejected claims. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *E.g.*, *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). "The proposed modification cannot render the prior art unsatisfactory for its intended purpose." MPEP 2143.01. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01, *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

The Examiner also uses Narciso as evidence that (specifically) a nickel/titanium alloy (more generally, a material exhibiting little or no memory retention when bent), in general, is equivalent to stainless steel and tantalum (which are disclosed as suitable materials by Liprie '781). However, such a broad generalization is inappropriate. The Examiner improperly generalizes about the equivalence of different metals.

Rather, focus should be on whether the metals are equivalent for the particular constructions taught by the independent claims. With reference to the Nariciso patent, whether NITINOL, stainless steel or tantalum are equally suitable or not (in that for the application, the metals permit the construction to deflect and then return to their original position) as a deflecting wire within a steerable catheter is not determinative as to whether a nickel/titanium alloy (or indeed, a material that exhibits little or no memory retention when bent) is equally suitable (equivalent to) stainless steel or tantalum in the form of a housing tube for a source wire.

It is well known in the industry that stainless steel source wires tend to fail not only through repeated traversal of the tortuous regions of the body, but may also tend to kink or distort during single applications in particularly tortuous regions. By contrast, the shape memory characteristics of the nickel and titanium alloy housing tube, specifically, and materials exhibiting little or no memory retention when bent, more generally, of the presently presented claims lends a resiliency to the wire, permitting the wire to repeatedly and reliably traverse the tortuous regions of the body without risk of such distortion and kinking.

The Ishibe reference does not cure the deficiencies of Liprie '781 and Nariciso.

The Examiner's rejections should be withdrawn. Reconsideration and allowance is respectfully requested.

Further Claim Rejection of Claims 7, 8, 16 and 26 Under 35 U.S.C. 103(a) as Allegedly Being Obvious over Liprie '781 in View of Suthanthiran or Liprie '300.

The Examiner uses Suthanthiran to show that encapsulation of radioactive sources is generally known. However, the Examiner should note that the radioactive seed of

Suthanthiran is for direct placement within the body, not for inclusion within a flexible, elongated housing tube, as is required by claims 1 and 15.

Additionally, Suthanthiran does not describe a capsule, provided within a flexible, elongated housing tube, such as is required by claim 23. For this reason alone, the Examiner's rejection should be withdrawn with reference to claim 23.

As discussed above, Liprie '781 calls (1) for a radioactive source to be directly inserted within a housing tube between a backbone wire and a plug and (2) for the tube to be drawn down to secure each element in place. Liprie '781 teaches that the drawing down process removes all air space. This removal of air space prevents migration of radioactive flakes.

When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. *E.g.*, *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). "The proposed modification cannot render the prior art unsatisfactory for its intended purpose." MPEP 2143.01. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01, *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959).

The proper motivation to combine Suthanthiran and Liprie '781 is not present. Suthanthiran does not suggest the desirability of including the seed within any other devices, and Liprie '781 does not suggest the desirability of including within the wire what would ordinarily be designed for direct intracorporal use. The references do not

suggest the desirability of such combination, and the Examiner cannot draw such motivation from the Applicant's roadmap. As stated in W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983),

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. ... One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

Because the requisite motivation to combine is lacking, the Examiner's rejections should be withdrawn.

With reference to the rejection with regard to Liprie '781 in combination with Narciso and Liprie '300, Liprie '300 is presented by the Examiner to show that rounding of backbone wires or capsules is known in the art. However, the independent claims 1, 14 and 24 do not include any such limitations. Because the independent claims are patentable for the reasons described above, the Applicants need not address the teachings of the reference. Accordingly, the Examiner's rejection should be withdrawn.

If there are any charges with respect to this submission or otherwise, please charge them to Deposit Account No. 06-1130, maintained by the Applicant's attorneys.

Respectfully Submitted,

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